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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,070

08/22/2003

Michael Wayne Graham

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COOPER & DUNHAM, LLP  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/646,070	<b>Applicant(s)</b> GRAHAM ET AL.	
	<b>Examiner</b> Brian Whiteman	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/29/08, 10/10/08.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 48, 110, 114-136, 138-140 and 145-152 is/are pending in the application.
- 4a) Of the above claim(s) 139, 140, 145 and 150-152 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48, 110, 114-136, 138, 146-149 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/10/08, 7/29/08, 3/26/08, 1/31/08</u>                       | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 139, 140, 145 and 150-152 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/15/04.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 1/31/08, 10/10/08, 7/29/08, and 3/26/08 were filed after the mailing date of the Non-Final Rejection on 1/24/08. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Third-party submission filed under 37 CFR 1.99***

A third-party submission has been filed under 37 CFR 1.99 on 2/22/08 in the published application.

To ensure that a third-party submission does not amount to a protest or pre-grant opposition, 37 CFR 1.99 does not permit the third party to have the right to insist that the examiner consider any of the patents or publications submitted. Furthermore, if the submission or part of the submission is not in compliance with 37 CFR 1.99, that noncompliant submission or part thereof will not be entered in the application file.

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Therefore, unless the examiner clearly cites a patent or publication on form PTO-892, Notice of References Cited and such reference is used in a rejection or its relevance is actually discussed during prosecution, consideration by the examiner of any patent or publication submitted in a third-party submission cannot be presumed.

If the applicant wants to ensure that the information in a third-party submission is considered by the examiner, the applicant should submit the information in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98. An individual who has a duty to disclose under 37 CFR 1.56 should also submit any material information contained in a third-party submission to the Office in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98 to ensure such material information is properly disclosed to the examiner.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 48, 107, 108, 110, 111, 114, 115, 116, 117, 118, 120, 121, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, and 146-149 remain rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al (US 6,506,559, cited on a PTO-1449).

The 102(e) reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising dsRNA comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The structural gene can comprise one or more strands of the nucleotide sequence (column 4). The nucleotide sequence may be at least 25 or 50 bases (column 8). The dsRNA may be formed by a single self-complementary RNA strand or two complementary RNA strands (column 7). With respect to a single self-complementary RNA strand, the self-complementary RNA strand would contain a hairpin. The hairpin would have an undefined number of nucleotides. The construct comprises a regulatory region including polyadenylation (columns 8-9). The vector can be introduced into a cancerous cell, including cancer cells found in humans and can be introduced into stem cells (column 8-10). A viral vector or lipid mediated carrier transport can be used as the vector (column 9). Fire et al. teaches using a phagemid to produce dsRNA (Column 18). The cell can comprise a

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target gene at risk from a pathogen including HIV or can be from several different types of animals (columns 4, 8, and 10). The target gene can be an endogenous from in a human cell (columns 4 and 10-11). The construct can comprise a structural gene with an intron. In addition, the structural gene can comprise a 5' or 3' untranslated region (column 20).

Applicant's arguments filed 10/10/08 and 7/29/08 have been fully considered but they are not persuasive.

In response to applicant's argument that the Fire does not enjoy a priority date before the instant application because the provisional of Fire teaches less than the patent of Fire and the last office action cites numerous portions of Fire et al. Patent which do not appear in the Fire et al. provisional, the argument is not found persuasive because the argument does not address whether or not Fire teaches the claimed product. Furthermore, the portions of Fire et al. patent that teach the claimed product are supported in the Fire et al. provisional. The applicant has not specifically pointed out what portions of the 102(e) rejection are not supported by the Fire et al. provisional.

In response to applicant's argument that the Fire et al. provisional does not disclose a "double stranded" molecule with an "interrupted palindrome", the argument is not found persuasive because as shown in exhibit C, a vector taught by Fire would contain the "interrupted palindrome sequence" resulting in a single self-complementary RNA, wherein each strand is connected by a non-complementary region of nucleotides. It appears that applicant is claiming the DNA construct that would have been used to make the dsRNA claimed by Fire. With respect to the argument that the genus of

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products taught by Fire cannot anticipate the claimed product directed to a species of the genus (see Exhibit G (Gross et al. 1982) and Exhibit H (Sanofi-Synthelabo v. Apotex)), the argument is not found persuasive because the genus of vectors is narrow and can only read on two species, vectors that express single stranded or double stranded nucleic acids or double stranded vectors or single stranded vectors. “When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated.” See Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). This is the case here. Fire et al. provisional teaches, “RNA was synthesized from phagemid clones (page 15, line 5).” The skilled artisan understands that phagemid clones can be used for double stranded replication. “For example, it has been held that a prior art genus containing only 20 compounds and a limited number of variations in the generic chemical formula inherently anticipated a claimed species within the genus because “one skilled in [the] art would... envisage each member ” of the genus.” See In re Petering, 301 F.2d 676, 681, 133 USPQ 275, 280 (CCPA 1962). Furthermore, applicant admits on page 20 of applicant’s argument that the “loop” of a self-hybridized RNA will form regardless of whether the nucleotides of the “loop” are self-complementary. NOTE: Dale et al. teach the RNA hairpin loops contain a mismatch in the loop region (RNA 6:608-615, 2000).



In response to applicant's argument that Fire et al. provisional does not specify whether the "transgenes" or "expression vector" disclosed on page 7 and page 11 could have an "interrupted palindrome" and the "interrupted palindrome" is an element which is distinct element from the "structural gene region" and the Fire et al. provisional does not disclose that the "single self-complementary RNA strand" has a central portion that is not "self complementary" and the interpretation that it does teach this region is arbitrary and hints of hindsight bias, the argument is not found persuasive because as shown in exhibit C, a vector taught by Fire would contain the "interrupted palindrome sequence" resulting in a dsRNA, wherein each strand is connected by a non-complementary region of nucleotides. It appears that applicant is claiming the DNA construct that would be used to the make dsRNA claimed by Fire.

In response to applicant's argument that the "loop" the examiner continues to rely on will form regardless of whether the construct encoding the hairpin contains an interrupted palindrome and a construct without an interrupted palindrome will encode a single-stranded self complementary RNA without a non-self-complementary segment between the complementary segments and such a self-complementary single-stranded RNA would nonetheless form a "loop" when in a hairpin confirmation and such constructs are clearly encompassed by Fire et al. provisional, the argument is not found persuasive because as set forth in Exhibit C and Dale et al. (supra), the vector used to produce a single self-complementary RNA strand would form a hairpin with non-complementary nucleotides. "For example, it has been held that a prior art genus containing only 20 compounds and a limited number of variations in the generic

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chemical formula inherently anticipated a claimed species within the genus because “one skilled in [the] art would... envisage each member ” of the genus.” See *In re Petering*, Id. Furthermore, applicant’s argument that Fire encompasses dsRNA molecules containing a loop having a loop containing complementary nucleotides and does not argue that construct of Fire et al. does not encompass a dsRNA molecule containing a loop having non-complementary nucleotides. Thus, there is nothing of record to support applicant’s assertion that vector taught by Fire et al. only encompasses dsRNA constructs having a loop containing only complementary nucleotides.

In response to applicant’s argument that the claimed invention constitutes an unpredictable improvement over the subject matter claimed as well as the subject matter disclosed by Fire et al., the argument is not found persuasive because unpredictability is not considered under a 102 rejection. “Evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based.” See *In re Wiggins*, 488 F.2d 538, 543, 179 USPQ 421, 425 (CCPA 1973). In addition, the product taught in the prior art appears to have the same structural limitations as the claimed product.

In response to applicant’s argument that on page 59, lines 27-29, the specification reports an experiment evidencing the unpredictable improvement resulting from the use of an interrupted palindrome and direct palindrome sequences were unstable and using an interrupted palindrome sequence overcome the stability problem

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in the context of applicant's invention, the argument is not found persuasive because in view of Exhibit C, the product (vector used to make the single self complementary strand) taught by Fire et al would read on the claimed product. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). "Evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based." See *In Re Wiggins*, Id.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48, 110, 116, 117, 119, 122, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. (US 6,506,559, cited on a PTO-1449) taken with Dietz (US 5,814,500, of record). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising dsRNA comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The dsRNA may be formed by a single self-complementary RNA strand or two complementary RNA strands (column 7). The construct comprises a regulatory region including polyadenylation (columns 8-9). The nucleotide sequence may be at least 25 or 50 bases (column 8). The vector can be introduced into a cancerous cell, including cancer cells found in humans (column 9-10). A viral vector or lipid mediated carrier transport can be used as the vector (column 9). The cell can comprise a target gene at risk from a pathogen including HIV or can be from several different types of animals (columns 4, 8, and 10). The target gene can be an endogenous from in a human cell (columns 4 and 10-11). The construct can comprise a structural gene with an intron. In

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addition, the structural gene can comprise a 5' or 3' untranslated region (column 20).

The structural gene can comprise one or more strands of the nucleotide sequence (column 4). However, Fire does not specifically teach a retroviral vector comprising the dsRNA construct.

However, at the time the invention was made, Dietz teaches making a retroviral vector for expressing inhibiting RNA (column 8). Dietz further teaches using a SV40 early, RSV or CMV promoter to express the RNA (column 6).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Dietz, namely to produce a retroviral vector comprising the dsRNA construct. One of ordinary skill in the art would have been motivated to combine the teaching for integration of the dsRNA into the genome of an animal cell.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Dietz, namely to produce a dsRNA construct comprising a CMV, SV40 early, or RSV promoter. One of ordinary skill in the art would have been motivated to combine the teaching to sufficiently express the dsRNA in animal cells.

In view of Fire and Dietz, one of ordinary skill in the art would have had a reasonable expectation of success for producing the product

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 10/10/08 and 7/29/08 have been fully considered but they are not persuasive for the reasons set forth in the response to applicant's arguments under the 102 (e) rejection using Fire and no additional arguments against the combination of references that provide the basis for the 103(a).

In response to applicant's argument that the claimed synthetic gene with an interrupted palindrome sequence is an unpredictable improvement over Fire et al (page 59, lines 27-29 of the specification), the argument is not found persuasive in view of Exhibit C, the product (vector used to make the single self complementary strand) taught by Fire et al. would read on the claimed product. "Obviousness does not require absolute predictability, however, at least some degree of predictability is required." See MPEP 2143.02. This is the case here. The material taught in the Fire et al. and Dietz et al. reads on the claimed invention. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." See **KSR v. Teleflex**, 550 U.S. \_\_\_, 127 S. Ct. 1727 (2007).

Claims 133, 136, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al (US 6,506,559, cited on a PTO-1449) taken with Ladner et al (US 5,198,346, of record). Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). A viral vector can be used as the vector (column 9). However, Fire does not specifically teach separating a construct

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comprising the structural gene sequences with a stuffer sequence, wherein the sequence is 10-50, 50-100, or 100-500 nucleotides in length.

However, at the time the invention was made, Lander teaches using a stuffer fragment having above about 10 nucleotides to introduce a stop codon or a unique restriction site (column and Table 704).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Ladner, namely to produce a construct comprising a structural gene with a stuffer sequence having above about 10 nucleotides. One of ordinary skill in the art would have been motivated to combine the teaching to introduce a termination site after the sense strand or a unique restriction sequence for cloning purposes for adding additional sequences to the construct.

In view of Fire and, one of ordinary skill in the art would have had a reasonable expectation of success for producing the product

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 7/29/08 and 10/10/08 have been fully considered but they are not persuasive for the reasons set forth in the response to applicant's arguments under the 102 rejection.

In response to applicant's argument that the combination of Fire and Ladner is arbitrary at best and hints of hindsight bias, the argument is not found persuasive because the rejection contains a reason for combining the references and the applicant

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does not address why the motivation is not considered proper or why one of ordinary skill in the art would consider making the claimed product predictable. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Both are the case here. Fire teaches a construct for making dsRNA molecules and contemplated the molecules having more than one strand. Ladner teaches how to introduce a stuffer that can be used for inserting additional sequences into the construct taught by Fire.

In response to applicant's argument that the claimed synthetic gene with an interrupted palindrome sequence is an unpredictable improvement over Fire et al (page 59, lines 27-29 of the specification), the argument is not found persuasive because in view of Exhibit C, the product (vector used to make the single self complementary strand) taught by Fire et al would read on the claimed product. "Obviousness does not require absolute predictability, however, at least some degree of predictability is



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required.” See MPEP 2143.02. This is the case here. The material taught in the Fire et al. and Dietz et al. reads on the claimed invention. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” See **KSR v. Teleflex**, 550 U.S. \_\_\_, 127 S. Ct. 1727 (2007).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48, 107, 110, 111, 114-121, 124-136, 138, and 146-149 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 11-15, and 19-21 of Patent No. 6,573,099. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a construct capable of producing dsRNA.

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Applicant's arguments filed 7/29/08 have been fully considered but they are not persuasive because applicant defers discussion of the provisional rejections until the rejections are the only rejections remaining.

Claims 48, 107, 110, 111, 114-121, 124-136, 138, and 146-149 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56, 59, 60, 62, 63, 65-67, 77-90, 95-101, and 107 of copending Application No. 09/646,807. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims read on an animal cell comprising a construct comprising two identical sequences to a target gene in an animal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 7/29/08 have been fully considered but they are not persuasive because applicant defers discussion of the provisional rejections until the rejections are the only rejections remaining.

Claims 48, 107, 110, 111, 114-121, 124-136, 138, and 146-149 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims from copending Application Nos. 10/346,853 and 11/364,183. Although the conflicting claims are not identical, they are not patentably distinct from each other because the set of claims from '853 and '183 read on the instant claims

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directed to an animal cell comprising a construct comprising two identical sequences to a target gene in an animal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 7/29/08 have been fully considered but they are not persuasive because applicant defers discussion of the provisional rejections until the rejections are the only rejections remaining.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number 571-272-

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0764. The examiner can normally be reached on from 6:30 to 4:00 (Eastern Standard Time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Brian Whiteman/  
Primary Examiner, Art Unit 1635